

DEPARTMENT OF HEALTH AND HUMAN SERVICES

J. 1 1995

Dr. W. Martin Strauss  
Agricultural Regulation Director  
Monsanto Company  
Suite 1100  
700 14th Street, NW  
Washington, DC 20005

Dear Dr. Strauss:

This is in regard to your consultation with FDA on your Bollgard™ Cotton lines 531, 757, and 1076 which are genetically modified to be resistant to certain lepidopteran pests including: cotton bollworm, tobacco budworm, and pink bollworm. The new cotton varieties have been rendered resistant to these lepidopteran pests by expression of a pesticidal protein (*B.t.k.* protein, product of the *cryIA(c)* gene) from *Bacillus thuringiensis* subspecies *kurstaki*.

As part of bringing your consultation with FDA regarding these products to closure, you submitted a summary of your safety and nutritional assessment of new cotton line 531 on November 21, 1994. On February 27, 1995, you also made a detailed oral presentation of the data that supported this submission and submitted a summary of your safety and nutritional assessment of new cotton lines 757 and 1076. It is our understanding that these communications were intended by Monsanto to inform FDA of the steps taken to ensure that these products comply with those legal and regulatory requirements that fall within FDA's jurisdiction. Further, based on the safety and nutritional assessment you have conducted, it is our understanding that you have concluded that these new cotton varieties are not materially different in composition, safety, or any other relevant parameter from cotton varieties currently on the market and that they do not raise issues that would require premarket review or approval by FDA. All materials relevant to this consultation have been placed in a file that has been designated BNF 0013 and that will be maintained in the Office of Premarket Approval.

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Based on the description of the data and information presented during the consultation, the new cotton varieties do not appear to be significantly altered within the meaning of 21 CFR 170.30(f)(2). We have no additional questions concerning these products at this time. However, as you are aware, it is Monsanto's continued responsibility to ensure that foods the firm markets are safe, wholesome and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/s/

Alan Rulis, Ph.D.  
Acting Director  
Office of Premarket Approval  
Center for Food Safety  
and Applied Nutrition

cc: HFS-200 HFS-205 HFS-206 HFS-226 HFS-235 HFS-246  
HFS-247 HFS-013 HFV-221 BNF 0020